



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination and declaration regarding emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning

AGENCY: Department of Health and Human Services, Office of the Secretary

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On April 11, 2017, the Secretary determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves nerve agents or certain insecticides (organophosphorus and/or carbamate).

On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination and declaration are effective April 11, 2017

FOR FURTHER INFORMATION CONTACT: George Korch, Ph.D., Acting Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202)

205-2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of the U.S. Department of Health and Human Services (HHS), may issue an Emergency Use Authorization (EUA) authorizing 1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or 2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: 1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a chemical, biological, radiological, or nuclear (CBRN) agent or agents; 2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act¹ sufficient to affect national security or the health and security of United States citizens living abroad; 3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a CBRN agent or agents; or 4) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or

¹ 42 U.S.C. § 247d-6b(c).

the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.²

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

The Centers for Disease Control and Prevention (CDC) requested that the FDA issue an EUA for use of an injectable treatment for nerve agent and certain insecticide (organophosphorus and/or carbamate) poisoning to support preparedness and response to potential public health threats posed by these agents and compounds. At this time, FDA-approved injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning are not available to replenish the Department's Strategic National Stockpile³ inventory when the products in the current inventory expire. Pending the availability of such products, an EUA will facilitate ensuring that the products are available in the event of a public health emergency involving nerve agent or certain insecticides (organophosphorus and/or carbamate). The determination of a significant potential for a public health emergency, and the declaration that circumstances exist justifying the authorization of emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning by the

² As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, the Secretary may make determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary is no longer required to make a determination of a public health emergency in accordance with section 319 of the PHS Act, 42 U.S.C. § 247d to support a determination or declaration made under section 564 of the FD&C Act.

³ 42 U.S.C. § 247d-6b(a).

Secretary of HHS, as described below, enables the FDA Commissioner to issue an EUA for certain injectable treatments for emergency use under section 564 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On April 11, 2017, pursuant to section 564 of the FD&C Act, I determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves nerve agents or certain insecticides (organophosphorus and/or carbamate). 1

III. Declaration of the Secretary of Health and Human Services

On April 11, 2017, on the basis of my determination of a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves nerve agents or certain insecticides (organophosphorus and/or carbamate), I declared that circumstances exist justifying the authorization of emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of any EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the Federal Register as required under section 564 of the FD&C Act.

Dated: April 11, 2017.

Thomas E. Price

Secretary

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